

## **REMARKS**

In the Office Action dated April 21, 2004, the drawings were objected to under 37 C.F.R. §1.84(r) because lead lines for reference characters 6A and 6B were not included in Figure 1. Figure 1 has been amended to include such lead lines.

A typographical error in the title was noted by the Examiner, and the title at page 1 of the present specification has been corrected. Applicant notes, however, that the title used in the database of the Patent and Trademark Office is taken from the Declaration, and the title in the present Declaration did not contain the typographical error that was present in the title in the specification. Nevertheless, Applicant of course has no objection to making this correction.

The Examiner required the use of shorter sentences in the Abstract, and the Abstract has been revised to respond to this requirement.

Typographical errors also were noted in claims 1 and 2, which have been corrected in addition to the further revisions in claims 1 and 2.

In the rejection of claims 1 and 2, the Examiner stated that Applicant has essentially claimed a statement of intended use, which the Examiner stated followed from the use of the phrase "... adapted to..." in claim 1. The Examiner stated this is a statement of intended use, which is not given patentable weight in apparatus claims. The use of the phrase "adapted to" in claim 1 occurs only at two locations, and at each location the phrase is used for the purpose of describing the inter-relationship of an apparatus component to the patient. This is the standard technique in the Examiner's examining group for avoiding "claiming the patient." Since it is not the intent of the Applicant to claim the patient as part of the apparatus, the Examiner's statement that this portion of the claim is not being given patentable weight is acknowledged and agreed with, however, this is immaterial to the

patentability of the remainder of the subject matter of claim 1 which, as discussed below, is set forth in the proper form for giving patentable weight to all of the claim limitations, despite the use of functional language.

The undersigned counsel for the Applicant has prosecuted several hundred patent applications in examining groups responsible for examining applications in ventilation and anesthesia technologies, and in many instances has been actually required by Examiners to use the phrase “adapted to” for exactly the purpose it is used in the present application, namely to avoid “claiming the patient” in an apparatus claim (as opposed to a method claim, wherein method steps claiming interaction with a living subject are permissible).

Applicant respectfully submits that the description of the functions set forth in claims 1 and 2 are compatible with the guidelines provided in MPEP §2114 with respect to claims employing functional language. As that section makes clear, it is not necessary to specifically invoke the provisions of Section 112, sixth paragraph relating to “means-plus-function” claim language in order for functional language in a claim to be given patentable weight. Applicant submits that the various functions described in claims 1 and 2 of the present application are not merely statements of intended use, but describe actual operation and inter-relation of the apparatus components set forth in those claims. Particularly in the context of electronic control, it is difficult to avoid some level or degree of functional description, and MPEP §2114 recognizes as much.

Moreover, MPEP §2114 further states that, with regard to rejecting a claim embodying functional language, it is not sufficient simply to cite a reference that is capable of performing the claimed function. The claim must still be analyzed with regard to the interaction of each particular function with the other functions and

structure in the claims, and in this regard the rejection of a claim embodying functional language must be formulated no differently from any other patent claim.

Nevertheless, claims 3 and 4 have been added which are method claims tracking claims 1 and 2. Applicant recognizes that, for restriction purposes, by filing the original application with apparatus claims, Applicant has implicitly elected the apparatus claims, however, Applicant submits that in view of the close tracking of the language between apparatus claims 1 and 2 and method claims 3 and 4, there is no need to consider those claims in the context of a restriction requirement. The same prior art must be searched and the same patentability considerations must be made for the apparatus claims as for the method claims. Examination of all claims in the present application is therefore respectfully requested.

Claims 1 and 2 were rejected under 35 U.S.C. §102(b) as being anticipated by Leenhovem, Huygen et al or Stenzler. These rejections are respectfully traversed for the following reasons.

Although of these references disclose method and devices for regulating breathing assistance to a patient, only the Huygen et al reference is directed to a method and an apparatus associated with a procedure that could be characterized as recruitment, or a recruitment maneuver. As described at pages 1 and 2 of the present specification, an inherent property of a lung is a tendency to collapse, but for a healthy lung this tendency is countered by the chest and a natural substance, called surfactant, in the lungs. Certain pathological conditions, however, can result in a complete or partial collapse of a lung (a condition known as pneumothorax), and if this occurs a recruitment maneuver is required to apply relatively high pressure to re-open the lung. As also explained in this portion of the present specification, after recruitment has taken place, and the recruited lung is subjected to mechanical

ventilation, there is a need to determine how the recruited lung develops after recruitment or during treatment. In particular, it is important to determine the recruitable volume of the lung. This is important, for example, because the use of a Positive End Expiratory Pressure (PEEP) is common during mechanical ventilation to prevent a collapse from occurring or re-occurring. PEEP itself is not a recruitment maneuver, since it is not used after a collapse has occurred, but is used as a preventative technique. If the lung has become permanently or semi-permanently damaged due to the collapse or other pathological conditions, however, the elevated pressure that is applied in PEEP may be too severe for the existing recruitable volume of the lung, which is why there is a need for monitoring this recruitable volume.

Since neither the Leenhoven reference nor the Stenzler reference is concerned with recruitment, neither of those references discloses any need, or any technique, for monitoring the recruitable volume of a lung. The methods and apparatuses respectively disclosed in those references monitor volume and pressure supplied in the context of breathing assistance to a patient, but, as described above, the special context of recruitment and determining the recruitable volume of a lung, are nowhere discussed in either of those references. Therefore, even though the Leenhoven and Stenzler references employ components such as a control system, a pneumatic unit and a measurement unit, there is no reason to assume that those components inherently operate in the Leenhoven reference or in the Stenzler reference in the manner set forth in the claims of the present application, nor is there even any reasons to assume that the components in those references would be capable of operating in that manner.

There clearly is no explicit disclosure in either the Leenhoven reference or the Stenzler reference regarding a method or an apparatus as set forth in the claims of the present application, and therefore the Examiner's only basis for an anticipation rejection based on those references must be inherency. As the Federal Circuit has stated many times, however, in order to substantiate an anticipation rejection based on inherency, it is not sufficient to merely state that references are capable of operating in a particular manner, or could be made to operate in a particular manner, it is instead necessary to provide evidence that the allegedly anticipating reference, despite the lack of an explicit disclosure, *necessarily* incorporates each and every claim limitation of the claim against which it is applied.

Therefore, Applicant respectfully submits that the Examiner has not properly substantiated an anticipation rejection based on either of the Leenhoven or Stenzler references, since neither of those references is in any manner concerned with lung recruitment.

The Huygen et al reference is concerned with a method and an apparatus for opening a partially or completely collapsed lung, even though the specific term "recruitment" is not used. The method and apparatus in the Huygen et al reference, however, are not concerned with determining the recruitable volume of a lung, but only are concerned in determining when the opening (recruitment) procedure has achieved the desired results of opening the alveoli. In the Huygen et al reference, this opening is determined by monitoring the crackling sound, using a microphone, that characterizes when an individual alveoli opens.

Since the Huygen et al reference is concerned with only determining when a recruitment maneuver can be considered to be successful, and thus completed, there is no disclosure therein regarding how to determine when the recruitable



volume of the lung is so that the recruitment maneuver can be undertaken without endangering the patient by overtaxing a lung having a low recruitable volume. The Hugyen et al reference therefore, does not anticipate any of the claims of the application.

Although Applicant submits that the aforementioned knowledge of those ordinary skill in the art relating to recruitment is well known, and is adequately described in the introductory portion of the present application, a printout of a website for Critical Care Medicine Tutorials is attached hereto, specifically providing background information regarding the definition of and conventional techniques for recruitment maneuvers. This attachment substantiates all of the above statements regarding recruitment, as well as the statements in the original specification.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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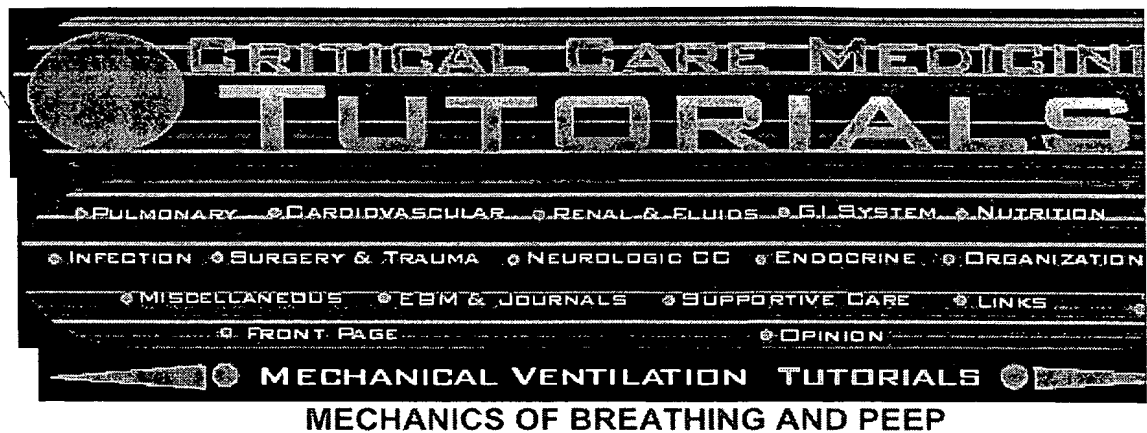
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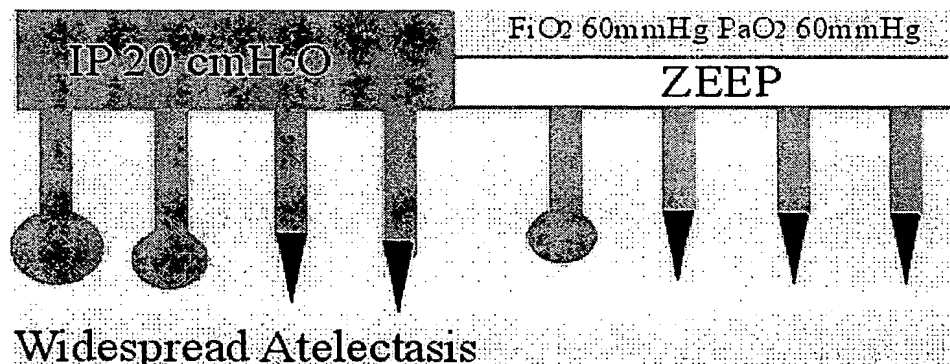
### What is a recruitment maneuver?

- **Recruitment maneuvers are used to reinflate collapsed alveoli, a sustained pre tidal ventilation range is applied, and PEEP is used to prevent derecruitment**

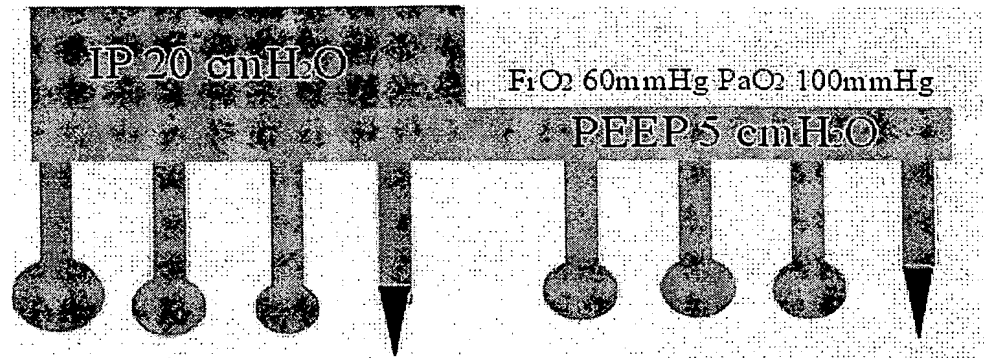
There is strong evidence to support the hypothesis that PEEP has a protective effect in and probably in the prevention of ventilator induced lung injury. The reasons proposed for Curtailment of quantitative and qualitative surfactant depletion 2. Reduced shearing stress tissues, reduced parenchymal injury and cytokine release. We also know that to optimize with modern low stretch (low tidal volume) ventilation strategies, the lung needs to be compliant.

PEEP only prevents derecruitment. In the past when large tidal volumes were used to ventilate lung units were probably opened the repetitive high pressure expansion. Many "sticky" alveoli reopen in the normal tidal volume and protective pressure range.

If you have ever witnessed re-expansion of the lung (or performed it) during thoracic surgery, you have noticed that the most effective way of performing this maneuver is to apply long, slow inflations (rapid "bagging" with large tidal volumes is quite ineffective): the lung segments expand. This method should be applied to lung recruitment in intensive care. Every time a patient is disconnected from a ventilator, the lungs derecruit – whole segments of the lung will collapse, and will require reinstatement of previous ventilator settings. A recruitment maneuver is required.

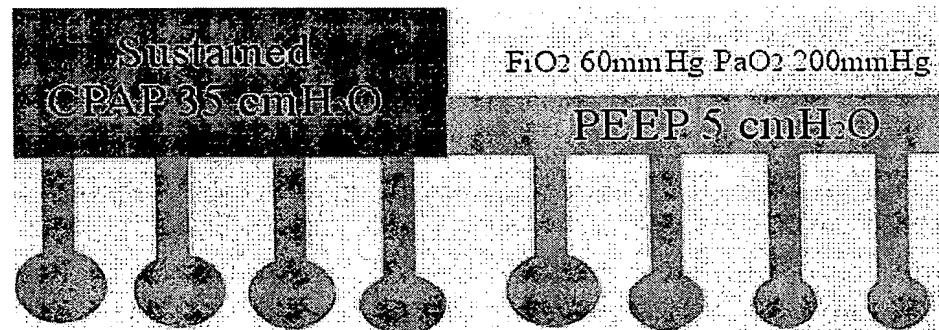


In the absence of PEEP many alveoli expand and collapse during the respiratory cycle. Alveoli that do not participate in gas exchange.



Recruitment and prevention of derecruitment by adding PEEP, "sticky" alveoli remain collapsed.

Using PEEP, the alveoli that open in inspiration remain recruited. However some "sticky" collapsed.



Remaining alveoli are recruited by applying a sustained inflation maneuver.

Application of sustained pressure to the lung pops open the residual alveoli, and PEEP ma

### Recruitment Maneuvers

Anesthesiologists routinely perform such maneuvers in the operating room, albeit in a manner (a tidal volume is delivered through a manual breathing system and held, the air measured). There are many methods of performing sustained inflation maneuvers in it being in complete control of the airway pressure.

Two factors influence whether or not recruitment maneuvers are successful: the pressure excess of the current plateau pressure, and the pressure must be sustained, in order to in long time constants. The most effective method of doing this is to apply CPAP to the air applied CPAP at 10cmH<sub>2</sub>O above the plateau pressure for 30 to 60 seconds to restore al Following the period of sustained inflation, the ventilation settings are returned to prev necessary to increase the PEEP, as the lung volumes from the same amount of PEEP a higher. A successful procedure will result in improved oxygenation, reduced end-tidal ( compliance.

On occasion, it may be necessary to increase the CPAP further to guarantee recruitment



above the pressure limit. Indeed sometimes very high pressures are required to recruit collapsed lung (Medoff (2000) and colleagues have reported a case where 40cmH<sub>2</sub>O of PEEP and 20cmH<sub>2</sub>O control was required to reinflate the lungs of a young woman with Streptococcal sepsis. PEEP required to prevent derecruitment in this patient was significantly higher than that previously reported.

Undoubtedly recruitment maneuvers will become an integral part of the management of ARDS (and stretch protocols). However the ideal level of PEEP required to prevent derecruitment remains to be established.

The following is a suggested batting order for recruitment maneuvers, adapted from Kacmarek (2000):

#### Performance of Recruitment Maneuvers:

1. Ensure hemodynamic stability.
2. Set the FiO<sub>2</sub> to 1.0
3. Wait 10 minutes.
4. Recruit with 30\* cmH<sub>2</sub>O CPAP for 30-40 seconds (\* or 10 cmH<sub>2</sub>O above the plateau pressure level).
5. If unresponsive, wait 15 minutes and then recruit with 35 cmH<sub>2</sub>O CPAP for 30 seconds.
6. If unresponsive, wait 15 minutes and then recruit with 40 cmH<sub>2</sub>O CPAP for 30 seconds.
7. If unresponsive, wait 15 minutes and then recruit with 20 cmH<sub>2</sub>O pressure control and 40 cmH<sub>2</sub>O CPAP for 2 minutes.
8. If the patient remains unresponsive, consider prone positioning.



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